



Ancillary Studies

Researcher Guidelines

Contextual Study



Contextual Ancillary Studies

This document outlines our guidelines and policies regarding contextual ancillary studies. Please read and follow the guidelines carefully or your proposal may be returned unreviewed.

What is an ancillary study?

An Ancillary Study is any study that adds data to Add Health that is beyond what is included in the activities of the core Add Health Study. Contextual ancillary studies merge secondary data sources or constructed variables to Add Health respondent records that requires unique identifiers (e.g., geocodes, school identifiers) to perform these linkages. Ancillary Study costs are supported by the investigator, and must be approved by Add Health before any grants for support are submitted for funding, and merges secondary data sources or constructed variables to Add Health respondent records that requires unique identifiers (e.g., geocodes, school identifiers) to perform these linkages.

To allow adequate time for submission, review, and revision, applicants are strongly encouraged to submit proposals at least six months in advance of an anticipated grant application deadline. Investigators who conduct an Ancillary Study must cover all costs incurred by the study, such as staff effort to prepare and document analysis files and integrate ancillary data into the Add Health Study. Most funding agencies require an approval letter included with a grant submission, therefore, **an ancillary study must be approved by Add Health before a grant to support it is submitted for funding.**

Although Ancillary Study investigators are not required to have previous experience with the Add Health Study, demonstrated familiarity with Add Health data and its study design will significantly enhance review of Ancillary Study proposals, within both Add Health and independent funding agencies.



Requirements

A. Investigator Requirements

Ancillary Study investigators must meet the following criteria:

- Have a PhD, MD, or other terminal degree.
- Hold a faculty appointment or research position at their institution.
- Work for an institution of higher education, a research organization, or a government agency.
- Have an institutional review board (IRB) that complies with applicable Federal regulations governing research involving human subjects.
- Demonstrate completion of research ethics training by all research team members who will work with the Add Health data.
- Have a demonstrated record of using sensitive data according to commonly accepted standards of research ethics.

B. Costs

Investigators proposing to conduct an ancillary study must cover all costs incurred by the study, such as preparing and documenting analysis files and integrating ancillary data into the Add Health Study. In most cases, the investigator will need to budget and establish a subcontract with the Add Health project to cover such costs. All ancillary data are reviewed for deductive disclosure risk, cleaned, and checked by Add Health staff. All dataset documentation must also be reviewed and codebooks created by Add Health staff. Please work with the Ancillary Studies Coordinator to create a cost estimate for your study. This should occur following concept proposal approval and before submission of a full application. Add Health staff must be contacted prior to submission of any proposal seeking funding from an external agency to provide cost estimates for budgeting these costs. In most cases, the investigator will need to budget and establish a subcontract with the Add Health project to cover such costs.

All ancillary studies are required to hold a restricted-use data contract. To apply for restricted-use data, please use the Add Health Contracts Management System (CMS) via the [CPC Data Portal](#). There are two types of restricted-use contract options – Secure Research Workspace (SRW) or Home Institution – dependent on your current or intended method of accessing Add Health restricted-use data.

C. Commercial Use of Add Health

Add Health does not allow for the commercial use of its data and will not approve ancillary studies that are subject to consulting or licensing obligations to another institution, corporation, or business entity.



D. Released Add Health Data

It is Add Health's expectation that ancillary studies make resulting data available to the Add Health community of data users.

E. Merging Secondary Data Sources onto Add Health Data

All secondary data appended to Add Health records become the property of the Add Health Project and will be made available to the research community according to the Data and Material Use Agreement (DMUA). Proposals to append extant data must include an explanation of:

- What data will be appended?
- An estimate of the number of variables to be added to the Add Health data.
- Description of the data sources (if extant) and variable constructs.

F. Ancillary Study Process

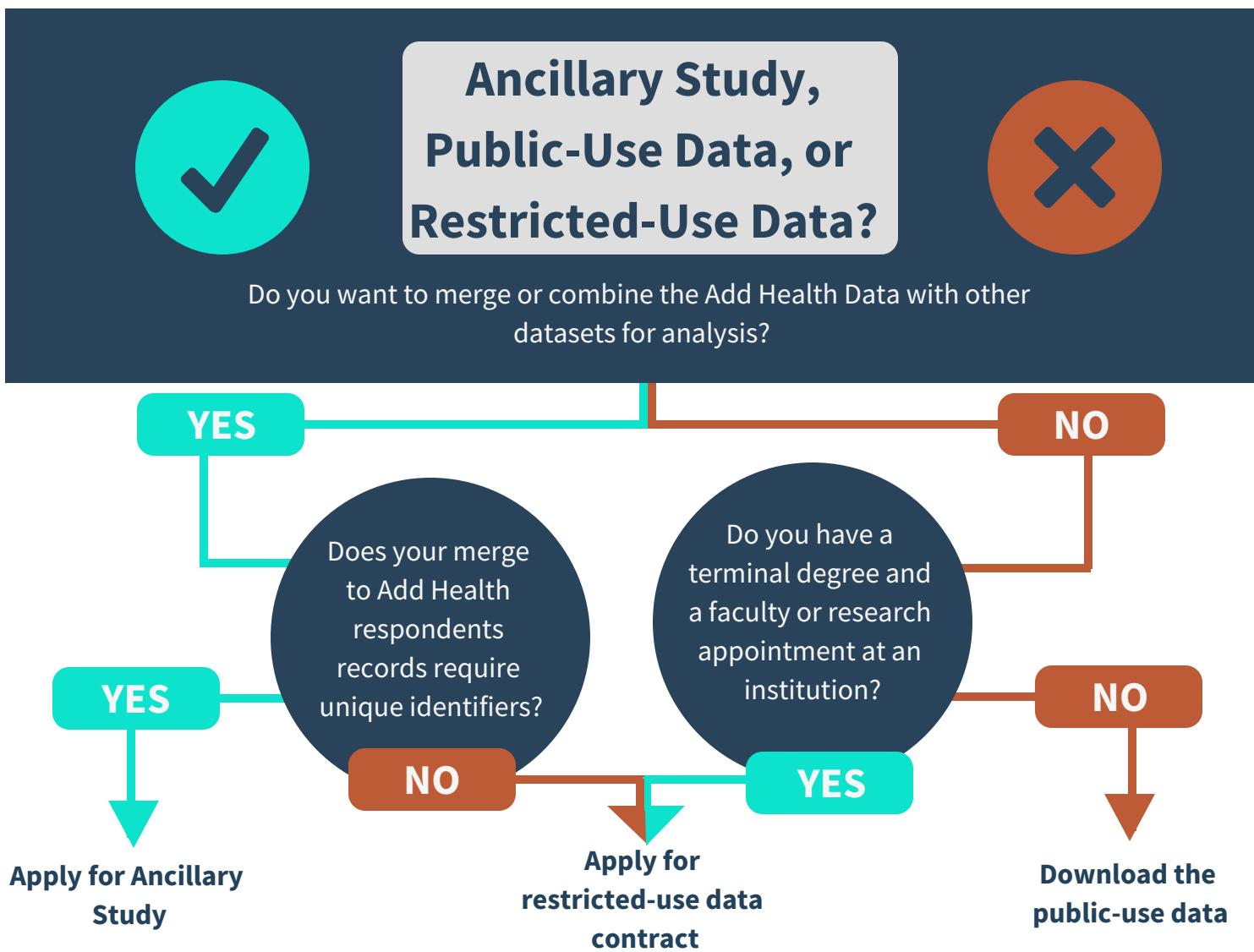
- Phase 1: Planning
 - Reach out to the [Ancillary Studies Coordinator](#) to start planning.
 - We recommend that investigators initiate planning for an ancillary study **6 months** before anticipated grant deadlines to allow time for planning, concept proposal, and full application review.
- Phase 2: Application
 - Initial concept proposal.
 - Cost estimate.
 - Full application.
- Phase 3: Funding and agreements
 - Apply for and obtain funding.
 - Include ancillary study letter of approval in application.
 - Complete necessary agreements, contracts, and approvals.
- Phase 4: Conduct your study
- Phase 5: Release of data



Phase 1: Planning

Before applying, investigators should:

- Contact the [Ancillary Studies Coordinator](#) to ask any questions.
- Review previously conducted and approved Ancillary Studies, which are available on the [Add Health Website](#), to ensure there is no significant overlap in concepts.
- Determine if you require an ancillary study or if your research can be conducted with a restricted use data contract. Please see the chart below for assistance.
- Review the [Add Health codebooks](#) for existing datasets to confirm data do not currently exist.
- Add Health Ancillary Study approval should be obtained before any grants including the planned activities are submitted.





Phase 2: Applying

Step 1 - Submit a 1-page concept proposal

Concept proposals are reviewed by the ancillary study review committee chair to determine the feasibility of the study. Applicants are provided feedback and, if approved to proceed, invited to submit a full application.

Step 2 - Submit an ancillary application

Your full application should describe the motivation for conducting the project in Add Health, scientific motivation and aims, approach, and timeline. Full applications are reviewed by at least two members of the ancillary studies review committee. The Ancillary Investigator must cover all costs incurred by the study such as preparing and documenting analysis files, data merge, codebook creation, and integrating ancillary data into the Add Health Study. Please work with the Ancillary Studies Coordinator to develop a cost estimate.

The review committee will evaluate the following:

- Add Health justification – The proposal should leverage the strengths of Add Health as a nationally representative population-based study of health. Proposals should be consistent with the policies of Add Health and minimize burden and risk to Add Health participants. The resulting data should add value to the study and benefit the user community.
- Importance of research – What is the significance, rationale, and scientific justification for the study?
- Approach – The scientific quality of the proposed work. Is the approach rigorous and feasible? Can the study be done well in the proposed timeframe?
- Expertise and resources – Are the investigators (and partners) sufficiently qualified to conduct the study and can their environments support the proposed work?



Add Health welcomes the addition of ancillary studies that have scientific merit. However, Add Health will not consider ancillary studies that:

- Duplicate or interfere with existing Add Health activities (including already approved ancillary studies).
- Adversely affect respondent cooperation in Add Health.
- Threaten the security of Add Health data and/or identities of Add Health respondents.
- Create an unacceptable diversion of Add Health study resources, including personnel or study samples.
- Jeopardize the public image of Add Health.
- Are not consistent with Add Health scientific objectives.

Outcomes of the review process may be:

- Accept - accepted applications will be provided a letter of approval for their grant application. Investigators should also finalize the budget with the Ancillary Studies Coordinator. Note that ancillary study approval indicates Add Health's agreement to work with study investigators to complete the proposed project, conditional on investigators securing the necessary funding to support the work. Approval does not indicate that investigators have the exclusive right to pursue proposed activities. In some instances, ancillary studies may be proposed and approved that overlap in their planned work. In such instances, Add Health will work with investigators to facilitate collaboration.
- Revise - if revisions are requested, they should be made in a resubmitted application, with tracked changes and comments, along with a response to the changes in a separate document.
- Reject - rejected applications will be provided with a final determination and reason for the decision.



Phase 3 - Funding and Agreements

Accepted applications will receive a formal written notice documenting Add Health's support for the project and guarantee for collaboration. This notice should be included in any external grant application to fund the project.

After receiving funding, the Ancillary Study Investigator will be required to complete the following distribution agreements prior to the release of any data by the Carolina Population Center (CPC)/University of North Carolina.

- Review, fill, and sign a Data and Material Use Agreement.
- Apply for a Restricted-Use Contract if one is not already in place by going to the CPC Data Portal.
- Provide proof of completion of research ethics training by all research team members who work with the Add Health data.
- Provide IRB approval for the ancillary study.

Annual Status Reports and Invoicing

After an Ancillary Study is funded and initiated, the PI is responsible for submitting annual progress reports of the study's status to Add Health until Add Health has released final ancillary data. These progress reports must summarize the study's activities, including:

- Progress of data collected to date
- Analysis in progress or completed
- Updates to scope, design, or methods
- Updates to timeline

Annual report forms will be sent out to investigators no later than June 1 of every year in the study period. These forms must be completed and returned to CPC no later than July 1 of the same year. Ancillary studies that fail to comply with the annual reporting requirement may be ineligible for renewal of their Add Health restricted-use contract and/or their Data and Material Use Agreement.

Invoices are submitted after the data has been merged and must be paid before the data can be released.



Phase 4: Conduct your study

Step 1: Schedule your launch meeting

Once your required documents are submitted and funding has been obtained, the Add Health Studies Coordinator will schedule a meeting with the Ancillary Study Investigator's team and Add Health to discuss your data plans and answer any questions.

Step 2: Data set preparation

After data collection is completed, it is time to assemble the planned contextual variables. Be sure to document data sources, variable construction and other relevant details. This information should include, but not be limited to:

- a detailed description of the source data.
- programming code documenting any variable construction.
- references for variable constructs (e.g., the reference for the standard scale used).
- documentation on the cleaning process to date.

Step 3: Submit clean data file for merge

Once Add Health has received the files, staff will examine the data for deductive disclosure risks and modify the data to reduce these risks. During this time, the following will be conducted:

- Ancillary data will be merged with existing Add Health data.
- Variable construction of the added data will be tested, researched, and reviewed. Consultants may be contacted, as necessary.
- Frequency distributions of the added variables will be evaluated for deductive disclosure.
- Cross tabulations of the new data with existing Add Health data will be run and reviewed.
- Logical associations among the new and existing data will be mapped out and evaluated.
- Documentation will be examined and edited.
- Decisions about modifications to the variables will be made in consultation with the Ancillary Studies Investigator. This may involve dropping variables, collapsing categories, or modifying the data in other ways to protect the identity of the study participants.
- A preliminary data file will be created.
- Codebooks following the Add Health standards will be created.



Step 4: Receive preliminary dataset

After the data is merged, the preliminary with masked participant IDs dataset will be placed on the secure research workspace (SRW) and the Ancillary Study Investigator will be given 30 days to review the data for errors. If an error is found, Add Health will make the necessary corrections and the Ancillary Study Investigator will be given an additional 30 days to review.

Once the data has been approved by the Ancillary Study Investigator, the preliminary dataset will be removed from the SRW and Add Health staff will begin preparations to release the final datasets. Because the final dataset is likely to be different from this preliminary dataset, the investigator is encouraged to develop & document analysis programs so they may be re-run against the final dataset that is released to the public.

Step 5: Prepare documentation

The Add Health Studies Coordinator will provide a User Guide template for the dataset that the Ancillary Study Investigator will need to create.

Step 6: Pay invoice

After the preliminary data has been approved, Add Health will conduct a final disclosure review and prepare the data for dissemination. The Ancillary Studies Coordinator will submit an invoice at this time for payment. Payment must be received before data can be released.



Phase 5: Release of the data

Once approval to disseminate is received from the Ancillary Study Investigator, a tentative release date will be set for the new data. The timeframe for release will be determined by the number of variables included in the ancillary dataset and the availability of Add Health staff to work on the final deductive disclosure risk review. The final data will be released to the entire user community at the same time. The Ancillary Study Investigator can request the data via the CPC Data Portal and begin publishing and presenting on the data.

The determination of what is included in the released file is made in collaboration with the Ancillary Study Investigator and their team. The Add Health Director/PI may assist in making decisions if needed.

Ancillary Study Investigators are not permitted to submit any manuscripts, abstracts, or presentations derived from the Ancillary Study for review before the release date of the final file. The Ancillary Study Investigator agrees to use only data from the final released file for analysis and submitted manuscripts, and any such work must include appropriate attribution to Add Health as specified in the Add Health restricted-use data agreement.

Applying for a Restricted-Use Data Contract

In order to receive preliminary ancillary data for review, the Ancillary Study investigator will need to apply for a restricted-use data contract. This contract is an agreement signed by two parties, the Ancillary Study Institution and UNC-Chapel Hill on behalf of Add Health. To apply for restricted-use data, please use the Add Health Contracts Management System (CMS) via the [CPC Data Portal](#). There are two types of restricted-use contract options – Secure Research Workspace (SRW) or Home Institution – dependent on your current or intended method of accessing Add Health restricted-use data.

Data Security

Protecting the identity of individual Add Health respondents is a critical issue for the Add Health study. Confidentiality of individually identifiable data about Add Health respondents must be assured. All data work will take place in the Secure Research Workspace (SRW). The SRW helps keep Add Health data more secure in our efforts to maintain the strict confidentiality of our participants. The SRW is available through remote access. All research and analysis will take place only within the SRW.

For detailed ancillary study data security obligations, see The Add Health website <https://addhealth.cpc.unc.edu/>.



Contextual Study Roadmap

Phase I

- Review Contextual Study Guidelines
- Review previously conducted and approved Ancillary Studies
- Determine if you need public-use data, restricted-use data, or to apply for an Ancillary Study
- Contact Coordinator to begin planning

6 months prior to funding submission

Phase II

- Submit one-page proposal
- Respond to reviewers feedback (resubmit if applicable)
- Submit full Ancillary Study application form
- Develop cost estimate
- Respond to reviewers feedback
- Receive decision

6 months prior to funding submission

Phase III

- Secure external funding
- Submit additional documentation, including DMUA, ethics training, HIPPA training, and IRB approval
- Apply for restricted-use data contract (if applicable)

Dependent on funding agency's timeline

Phase IV

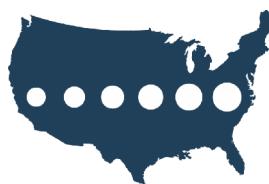
- Data merge and deductive disclosure review by Add Health
- Create user guide
- Review preliminary data and codebooks
- Approve data for release
- Pay invoice

6 to 12 months

Phase V

- Final data review by Add Health
- Data released to full user community
- Request the final released file using CPC Data Portal
- Prepare publications, manuscripts, and presentations using the final released file

6 to 8 weeks



Add Health

The National Longitudinal Study of Adolescent to Adult Health

Please contact and submit applications to:



Email:

addhealth_ancillary@unc.edu

For more information:



Website

<https://addhealth.cpc.unc.edu>



Address

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